



**Proven
Performance**

**A Decade
of Acid
Etched Surfaces**

 **STERI-OSS®**

From

 **Nobel Biocare**

Proven Success

Prior to the introduction of the first Steri-Oss® System threaded dental implant in 1986, surface research was initiated by Steri-Oss to develop a roughened titanium surface. The result of this research was a patented¹ two step acid etching procedure which significantly increased the surface area over that of machined titanium implants.

Acid Etched Since Inception

The Steri-Oss acid etched surface not only demonstrated increased roughness and therefore greater surface area, but also a very high surface energy which increased the ability of blood to spread out and disperse itself around the body of the implant. The Steri-Oss etched titanium threaded implant has featured this type of surface since its inception in 1986.

Figure 1a

Steri-Oss HL etched titanium implant
500x magnification

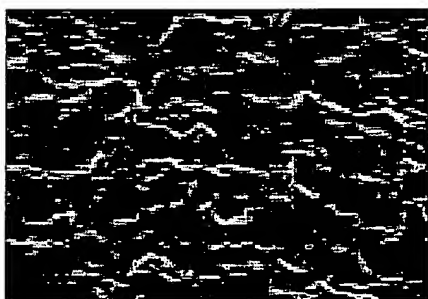
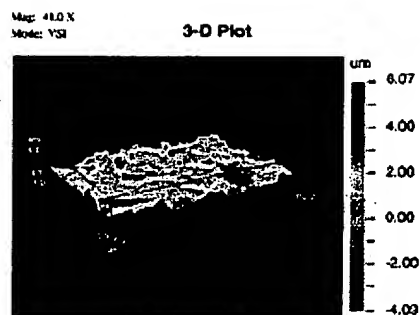
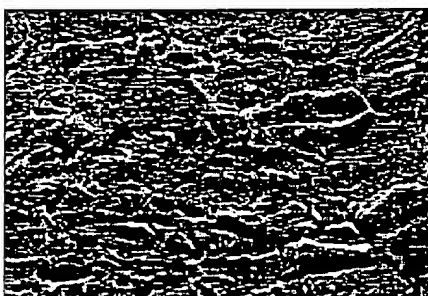


Figure 1b

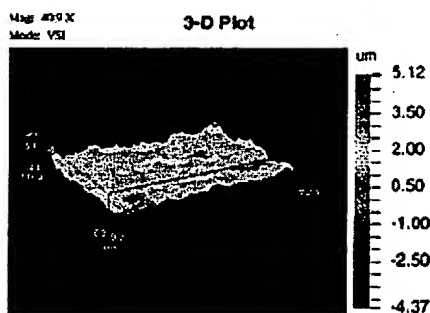
3i® Osseotite® etched titanium implant
500x magnification



Surface Statistics: Ra: 1130 nm

Figure 2a

Steri-Oss HL etched titanium implant Lot #967256



Surface Statistics: Ra: 939.62 nm

Figure 2b

3i® Osseotite® implant Lot #17910

Independent Laboratory Studies

Independent laboratories^{2,3} conducted evaluations of Steri-Oss and Osseotite® roughened surface dental implants. Scanning electron microscopy was used to evaluate topography (fig. 1a & 1b) and laser profilometry, which yields a 3D representation of the surface, was used as a quantitative measurement. This laser profiling (fig. 2a & 2b) demonstrates that the Steri-Oss etched titanium implants have more surface roughness and a greater surface area index than Osseotite®. These studies demonstrate the effectiveness of the patented Steri-Oss acid etching procedure.

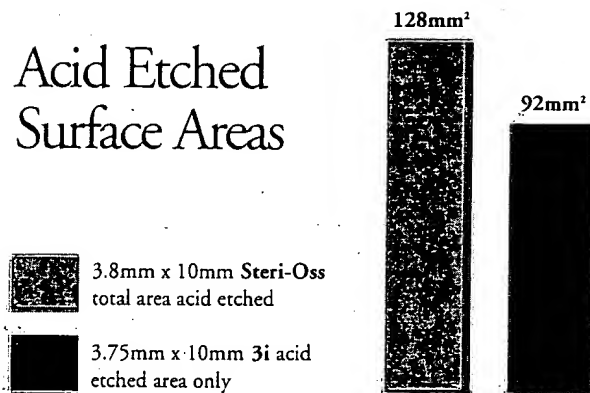
Superior Design

Acid Etched Surface Areas

In a three dimensional computerized modeling study, a comparison of surface area was made using dimensions from a commercially available Steri-Oss® System acid etched 3.8 x 10mm HL titanium implant and a commercially available 3.75 x 10mm acid etched Osseotite® implant.

The 3.8 Steri-Oss implant has the acid etched surface on all threads of the implant for maximum bone apposition while the Osseotite® implant has a machined surface on the top two threads and the remainder of the implant surface is acid etched.

Acid Etched Surface Areas



The acid etched surface area of the Osseotite® implant was 92mm² and the acid etched surface area of the Steri-Oss implant was 128mm², a 28% increase.

Acid Etched Surface Comparison

SEM's demonstrate the roughened acid etched surface of Steri-Oss and Osseotite® implants.

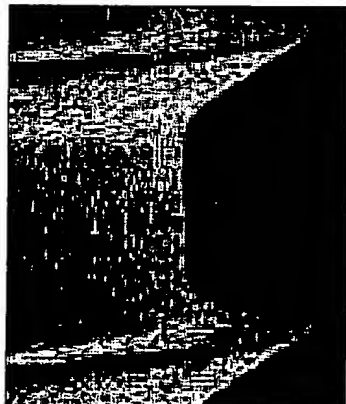


Figure 4a
SEM of Steri-Oss
acid etched
titanium surface
(100x)

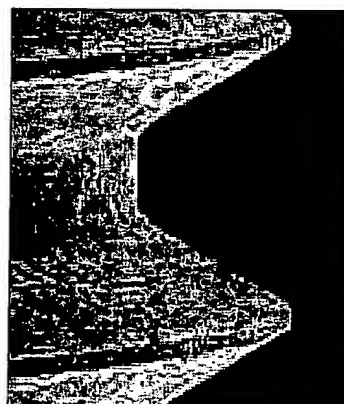


Figure 4b
SEM of Osseotite®
acid etched
titanium surface
(100x)

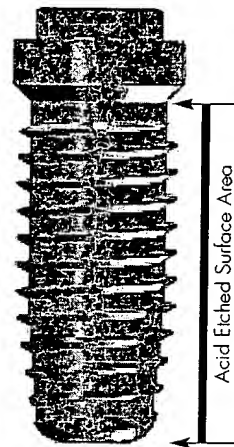


Figure 3a
Computer model of acid
etched surface area
of 3.8 x 10mm
Steri-Oss HL Implant

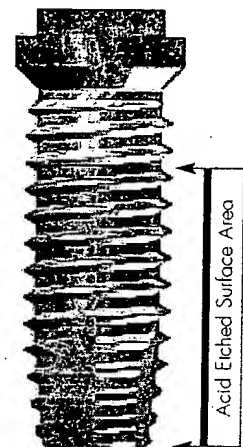


Figure 3b
Computer model of
acid etched surface area
of 3.75 x 10mm
Osseotite® Implant

Superior Design

Bone Volume Maximized Between Threads

In 1984, Steri-Oss® started the development of an improved thread design for use in soft bone. Instead of using a standard 60° (V Thread Design) machined thread, common to other implants, the thread profile of the Steri-Oss 3.8mm acid etched titanium implant was specifically designed to maximize bone volume between the threads while still maintaining the load transfer advantages that the 60° thread offers. The potential bone volume between the Steri-Oss threads is 32% more than the potential bone volume between the threads of standard 60° designs of the same depth and pitch.

One benefit of this greater bone volume between threads is a reduction in stripping on insertion of Steri-Oss implants.

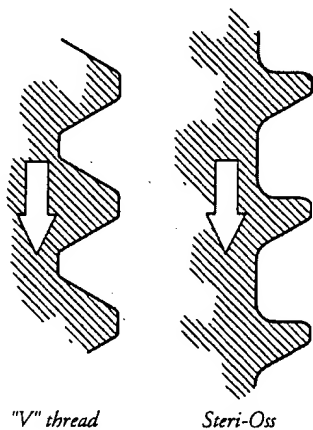


Figure 5

The potential bone volume between the Steri-Oss threads (right) is 32% greater than the same size standard "V" thread



Animal Studies

An animal study by Steflik et al¹ in dogs reported on histomorphometry of the dental implant bone interface in dogs after one and two years. One of the implants evaluated was the Steri-Oss 3.8mm acid etched implant with the large volume thread design.

Photomicrographs at six months, before loading, from this animal study clearly reveal the external thread pattern and the increased bone volume within the thread boundaries. 50% to 65% of the titanium surfaces were apposed by bone. (Figures 6a and 6b)

After 12 months of loading, osteocytes were routinely observed to be closely associated with the bone implant interface. (Figures 7)

The longer term study by Steflik et al¹ in dogs reported on the two year after loading histomorphometric results of the Steri-Oss acid etched dental implant bone interface. Computerized morphometric data presented the percent of the implant surface apposed directly by bone. After 24 months of loading, 64.0% of the titanium Steri-Oss acid etched surface was apposed by bone. (figures 8a and 8b)

Animal



Figure 6a

Photomicrographs of the tissue response to an unloaded Steri-Oss titanium acid etched threaded implant. Figure 6a uses normal transmitted light to show the significant amount of bone apposing the implant. However, areas of remodeling are also apparent (arrowhead). Note large bone volume between threads.



Figure 6b

Uses Nomarski differential interference of the same area to allow visualization of the banding patterns of the bone. Note large bone volume between threads. Original magnification 35X



Figure 7

High voltage electron microscopy demonstrates the direct apposition of mandibular bone to the Steri-Oss titanium implant loaded for 12 months. Osteocytes were found to extend cellular processes directly to the implant surface.

Implant Threaded Area

Area of remodeling

Figure 8a and 8b

Photomicrographs of the tissue response to a Steri-Oss acid etched titanium endosseous implant loaded for 24 months: routine transmitted light microscopy, figure (8a), shows significant amount of bone apposing the implant. Nomarski differential interference microscopy of the same area, figure (8b), shows lamellar patterns of the bone. Note large bone volume between threads.

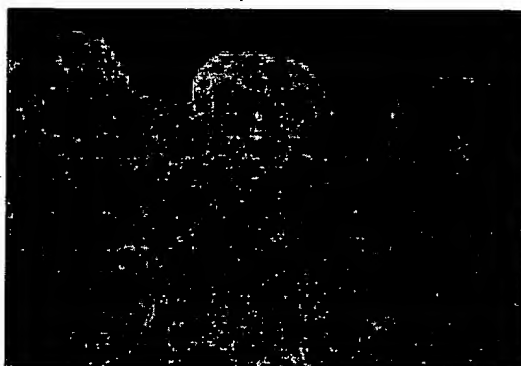


Figure 8a



Figure 8b

Implant Thread Area

Lamellar Bone

Clinical Research

Five Year Multi-Center Clinical Study Leads to Full ADA Acceptance

An international multi-center clinical study was initiated at three selected sites. The objective of the study was to demonstrate the ability of the Steri-Oss System acid etched threaded titanium implant to restore masticatory function in the partially and fully edentulous patient over a five year period. The study design complied with the ADA acceptance⁹ guidelines for dental implants.

This prospective, noncomparative study evaluated the safety and efficacy of the Steri-Oss 3.8 diameter threaded titanium endosseous dental implant with the patented acid etched surface. 524 implants in 196 patients completed at least 5 year post restoration follow-up. The one year success rate was 99.6% and 98.7% after two years. The five year life table success rate was 93.5%. The success rate in the posterior maxilla was 93.1%.

Full ADA acceptance was achieved after the ADA Council reviewed all of the clinical data from this study. This was the first full ADA acceptance granted for an acid etched threaded titanium implant.

Five Year Post-Restoration Life Table¹⁰ Success Rate

Time Period (Months)	Success Rate Life Table
0-12 months	99.6%
13-24 months	98.7%
25-36 months	96.5%
37-48 months	94.7%
49-60 months	93.5%

References

1. U.S. Patent #4826434
2. SEM study done by Photometrics, Huntington Beach, CA
3. Profilometry study done by Veeco, Tucson, AZ
4. Three dimensional computerized modeling study on file
5. Hurson S, Threaded Implant Design Criteria, Int J Dent Symp, June 1994, 38-40.
6. Steflik DE, Parr GR, Sisk AL, Lake FT, Hanes PJ. Histomorphometry of the Dental Implant-Bone Interface: One-Year results of a Comparative Investigation in Dogs. Int J Oral Maxillofac Implants 1994 5:501-512.
7. Steflik DE, Sisk AL, Parr GR, Lake FT, Hanes PJ, Berkery DJ, Brewer P. Transmission Electron and High-Voltage Electron Microscopy of Osteocyte Cellular Processes Extending to the Dental Implant Surface. J of Biomaterials Research, 1994 28:1095-1107
8. Steflik DE, Lake FT, Sisk AL, Parr GR, Hanes PJ, Davis HC, Adams BO, Yavari J, A Comparative Investigation in Dogs: 2-Year Morphometric Results of the Dental Implant-Bone Interface. Int. J. Oral Maxillofacial Implants 1996, 1, 15-25.
9. ADA acceptance submission on file
10. Life table analysis utilized the product-unit life method of Kaplan-Meier, (1958).
11. "American Seal certifies safety, effectiveness" Dental Teamwork, January-February 1955, 31-32

Clinical Research

Five Year Post-Restoration Life Table Success Rate

Anterior Maxilla	94.0%
Posterior Maxilla	93.1%
Maxilla, Total	93.5%
Anterior Mandible	96.4%
Posterior Mandible	90.5%
Mandible, Total	93.8%

Superior Performance in all Quadrants

The clinical evidence demonstrated the safety and superior performance of the Steri-Oss System acid etched threaded titanium implant in each anatomic region regardless of restoration types, single tooth, fixed or removable.

ADA Acceptance

The Meaning of ADA Acceptance

ADA acceptance gives dental professionals a reference point for safety and efficacy since the ADA guidelines for endosseous dental implants are the most rigorous in the world.

To be accepted, the Implant System—including the implant and abutment, the prosthesis and all surgical techniques—must demonstrate long-term valid clinical success rates. Consequently, surgeons and restorative dentists can be confident that their patients are receiving implant therapy with products that meet the highest standards for both safety and efficiency.

Threaded Implant Systems with ADA Acceptance

Nobel Biocare	Steri-Oss® Etched Titanium	YES
Nobel Biocare	Brånemark System® Titanium	YES
Implant Innovations Inc	3i® Osseotite®	NO

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